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MAR 23 2009

JONES DAY
222 East 41st Street
New York, NY 10017

In Re: Patent Term Extension
Application for
U.S. Patent No. 6,395,716

NOTICE OF FINAL DETERMINATION AND REQUIREMENT FOR ELECTION

A determination has been made that U.S. Patent No. 6,395,716, claims of which cover the human drug product TYZEKA® (telbivudine), is eligible for patent term extension under 35 U.S.C. § 156. The period of extension has been determined to be 442 days.

A single request for reconsideration of this final determination as to the length of extension of the term of the patent may be made if filed within one month of the date of this notice. Extensions of time under 37 CFR § 1.136(a) are not applicable to this time period.

Applicant also has applied for patent term extension of U.S. Patent No. 6,569,837 based on the regulatory review period for TYZEKA® (telbivudine).

When patent term extension applications are filed for extension of the terms of different patents based upon the same regulatory review period for a product, the certificate of extension is issued to the patent having the earliest date of issuance, unless applicant elects a different patent. In the absence of an election by applicant within one month of the date of this notice, and in accordance with 37 CFR 1.785(b), the application for patent term extension in U.S. Patent No. 6,569,837 will be denied. Accordingly, the application for patent term extension of the patent having the earlier date of issuance will be granted, i.e., a certificate of extension will be issued to U.S. Patent No 6,395,716. In the absence of a request for reconsideration, and if U.S. Patent No. 6,395,716 is elected, the Director will issue to the applicant a certificate of extension, under seal, for a period of 442 days in U.S. Patent No. 6,395,716.

The period of extension, if calculated using the Food and Drug Administration determination of the length of the regulatory review period published in the Federal Register of May 15, 2008 (73 FR 28119), would be 956 days. Under 35 U.S.C. § 156(c):

Period of Extension	=	½ (Testing Phase) + Approval Phase
	=	½ (2,009 - 697) + 300
	=	956 days (2.6 years)

Since the regulatory review period began July 1, 2000, before the patent issued (May 28, 2002), only that portion of the regulatory review period occurring after the date the patent issued has been considered in the above determination of the length of the extension period 35 U.S.C. § 156(c).

(From July 1, 2000, to and including May 28, 2002, is 697 days; this period is subtracted from the number of days occurring in the testing phase according to the FDA determination of the length of the regulatory review period.) No determination of a lack of due diligence under 35 U.S.C. § 156(c)(1) was made.

However, the 14 year exception of 35 U.S.C. § 156(c)(3) operates to limit the term of the extension in the present situation, because it provides that the period remaining in the term of the patent measured from the date of approval of the approved product plus any patent term extension cannot exceed fourteen years. The period of extension calculated above, 956 days, would extend the patent from August 10, 2019, to September 23, 2022, which is beyond the 14-year limit (the approval date is October 25, 2006, thus the 14 year limit is October 25, 2020). The period of extension is thus limited to October 25, 2020, by operation of 35 U.S.C. § 156(c)(3). Accordingly, the period of extension is the number of days to extend the term of the patent from its original expiration date, August 10, 2019, to and including October 25, 2020, or 442 days.

The limitations of 35 U.S.C. 156(g)(6) do not operate to further reduce the period of extension determined above.

Upon issuance of the certificate of extension, the following information will be published in the Official Gazette:

U.S. Patent No.:	6,395,716
Granted:	May 28, 2002
Original Expiration Date[1]:	August 10, 2019
Applicant:	Gilles Gosselin et al.
Owner of Record:	Idenix Pharmaceuticals, Inc.; Centre National de la Recherche Scientifique; and L'Universite Montpellier II
Title:	β-L-2'-Deoxy Nucleosides for the Treatment of Hepatitis B
Product Trade Name:	TYZEKA® (telbivudine)
Term Extended:	442 days
Expiration Date of Extension:	October 25, 2020

Any correspondence with respect to this matter should be addressed as follows:

[1]Subject to the provisions of 35 U.S.C. § 41(b).

By mail: Mail Stop Hatch-Waxman PTE
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P.O. Box 1450
Alexandria, VA 22313-1450.

By FAX: (571) 273-7728

Telephone inquiries related to this determination should be directed to Raul Tamayo at (571) 272-7728.

Mary C. Till
Legal Advisor.
Office of Patent Legal Administration
Office of the Deputy Commissioner
for Patent Examination Policy

cc: Office of Regulatory Policy
Food and Drug Administration
10903 New Hampshire Ave., Bldg. 51, Rm. 6222
Silver Spring, MD 20993-0002

Attention: Beverly Friedman

RE: TYZEKA® (telbivudine)
Docket No.: FDA-2007-E-0335